**UNITED NATIONS** **E**

**Economic and Social Council**

Distr.
GENERAL

E/CN.4/Sub.2/2001/13
27 June 2001

Original: ENGLISH

COMMISSION ON HUMAN RIGHTS
Sub-Commission on the Promotion and
Protection of Human Rights
Fifty-second session
Item 4 of the provisional agenda

# ECONOMIC, SOCIAL AND CULTURAL RIGHTS

## The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights

## Report of the High Commissioner

CONTENTS

| | | Paragraphs | Page |
|---|---|---|---|
| Introduction | | 1 - 4 | 3 |
| I. | A HUMAN RIGHTS FRAMEWORK FOR ANALYSING THE TRIPS AGREEMENT | 5 - 28 | 3 |
| A. | Introduction to the TRIPS Agreement | 5 - 9 | 3 |
| B. | Intellectual property rights and human rights | 10 - 15 | 5 |
| C. | Links between human rights and the TRIPS Agreement | 16 - 19 | 6 |
| D. | A human rights approach to the TRIPS Agreement | 20 - 28 | 7 |

GE.01-14345 (E) 270701

CONTENTS


| | | Paragraphs | Page |
|---|---|---|---|
| II. | THE TRIPS AGREEMENT AND THE RIGHT TO HEALTH | 29 - 58 | 10 |
| | A. Introduction | 29 | 10 |
| | B. States' obligations to respect, protect and fulfil the right to health | 30 - 36 | 10 |
| | C. Operational aspects of IP systems - medical research | 37 - 41 | 12 |
| | D. Operational aspects of IP systems - access to drugs | 42 - 50 | 13 |
| | E. The provision of HIV treatments in Brazil | 51 - 58 | 16 |
| III. | CONCLUSIONS AND RECOMMENDATIONS | 59 - 70 | 18 |

## Introduction

1. In its resolution 2000/7, the Sub-Commission for the Promotion and Protection of Human Rights requested the High Commissioner for Human Rights to undertake an analysis of the human rights impacts of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) of the World Trade Organization (WTO). In the same resolution, the Secretary-General was also requested to submit a report on the question of intellectual property rights and human rights. In relation to the Secretary-General's report, a note verbale dated 6 March was sent to States requesting information relevant to the report. That report is available as document E/CN.4/Sub.2/2001/12. Where relevant, information supplied in response to the note verbale has been included in the present report.

2. While the TRIPS Agreement could affect the enjoyment of several rights - in particular the right to food, the right to development, the human rights of indigenous peoples - the High Commissioner has decided to focus the report by examining the role of the TRIPS Agreement on the promotion and protection of the right to health. The High Commissioner has chosen the right to health as an entry point for an analysis of the TRIPS Agreement for several reasons. First, resolution 2000/7 recognizes that the TRIPS Agreement could affect the enjoyment of the right to health - in particular through its effect on access to pharmaceuticals.[1] Next, the High Commissioner views this as an opportunity to expand on work already being done by other international organizations in the area of the TRIPS Agreement and health - in particular by the World Health Organization (WHO), UNAIDS and WTO.

3. Finally, as the issue of trade agreements and health has been raised within the context of world conferences, the report can be situated within an identifiable international policy framework. Only last year, new initiatives for social development set by the General Assembly during the review of the outcome of the World Summit for Social Development invited the organizations of the United Nations system to integrate the health dimension into their policies and programmes, including through analyses of international trade agreements and trade in health goods and services (A/S-24/8/Rev.1, commitment 6, paras. 102 and 104). In the context of the special session of the General Assembly on HIV/AIDS in June 2001, the Secretary-General in his report (A/55/779, para. 48) has stated that "(g)lobally trade policy provisions need to be used more effectively to increase access to care [for people with HIV]. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with a guarantee of their quality".

4. The material for the report has been provided mainly through reports of the United Nations, the specialized agencies and WTO, as well as through consultations with some of the organizations referred to in the report.

## I. A HUMAN RIGHTS FRAMEWORK FOR ANALYSING THE TRIPS AGREEMENT

### A. Introduction to the TRIPS Agreement

5. The TRIPS Agreement was negotiated in the context of the Uruguay Round of multilateral trade negotiations under the General Agreement on Tariffs and Trade (GATT). The

TRIPS Agreement is the most comprehensive multilateral agreement that sets detailed minimum standards for the protection and enforcement of intellectual property rights and as a result it is a significant step in harmonizing national intellectual property (IP) systems. The Agreement is one of the agreements annexed to the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations which came into force in 1995. This means that all members of WTO are bound by the obligations under the TRIPS Agreement.

6. The minimum standards relate to the protection of: products and processes by patents; literary, artistic, musical and other works by copyright and related rights; industrial designs; trademarks; geographical indications; layout designs of integrated circuits; and undisclosed information such as trade secrets. The Agreement sets the minimum standards - requirements for the grant of rights, the time limitations on protection, permitted exceptions to the use of rights and modes of enforcement - to be implemented by each WTO member. The permitted exceptions will be referred to in greater detail below, however, the Agreement allows member States to adopt measures to protect public health and nutrition, to promote socio-economic and technological development and to protect against the abuse of intellectual property rights in certain cases. The interpretation of these exceptions is, in large part, up to the member States. The Agreement includes special treatment for developing countries in certain circumstances, including transitional flexibility for implementation. While developed countries should have implemented the Agreement by 1996, developing countries and countries in transition had until 1 January 2000 and least developed countries have until 2006 to complete implementation. The TRIPS Agreement recognizes the economic, financial, administrative and technological constraints of the least developed countries. It therefore provides the possibility of further extension of the transitional period.[2]

7. The Agreement also makes disputes between WTO members concerning respect for the minimum standards subject to the WTO dispute settlement procedures. In the case of a dispute, a panel of specially appointed trade experts interprets the provisions of the Agreement and issues a report. A decision of the panel may be subject to appeal to the WTO Appellate Body. If a party to a dispute fails to abide by a decision, the other party can impose trade sanctions on the member in breach upon authorization by the Dispute Settlement Body.

8. Finally, the Agreement includes a built-in mechanism for review. Review of the Agreement is also possible through the biennial Ministerial Conferences. The Ministerial Conference is the highest decision-making body of WTO and it can make decisions on all matters under any of the WTO Agreements, including the TRIPS Agreement. The third Ministerial Conference was held in Seattle in 1999. This year, the fourth Ministerial Conference will be held from 9 to 13 November in Doha, Qatar, and the issue of the TRIPS Agreement will, in all likelihood, be included on the agenda.

9. It should be noted that most WTO members already had some form of intellectual property protection in place prior to the TRIPS Agreement. The key difference is that the TRIPS Agreement provides comprehensive rules governing such protection which are subject to international legal interpretation and enforcement through an effective dispute settlement mechanism.

## B. Intellectual property rights and human rights

10. The starting point for a human rights analysis of TRIPS Agreement is article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the similarly worded article 27 of the Universal Declaration on Human Rights (the Universal Declaration).[3] Article 15 of the Covenant obliges States parties to respect, protect and fulfil people's cultural rights. The article identifies a need to balance the protection of both public and private interests in intellectual property. On the one hand, article 15 recognizes the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications. On the other hand, the same article recognizes the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. Taking these two aspects of article 15 together, ICESCR could be said to bind States to design IP systems that strike a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of authors and inventors in such knowledge.

11. The balance between public and private interests found under article 15 - and article 27 of the Universal Declaration - is one familiar to intellectual property law. Traditionally, States have awarded limited rights over new creations as a means of providing an incentive for innovation and for eventually ensuring public access to these creations. For example, a State may grant patents to inventors for a limited period in return for the disclosure of the invention. This ensures that the public will eventually have access to the invention, but during the period of protection, the patent holder has rights to exclude competitors from certain acts, such as making, using and selling a patented product. During this period, the patent holder has a market advantage which might allow higher prices to be charged over the technology, depending on the particular market conditions. This can be used to recoup research costs and could provide an incentive to continue inventing.

12. Consequently, there is a degree of compatibility between article 15 and traditional IP systems. However, the question essentially is where to strike the right balance.[4] Should greater emphasis be given to protecting interests of inventors and authors or to promoting public access to new knowledge? There are certain preconditions to a human rights approach to intellectual property protection which should be borne in mind.

13. First, a human rights approach requires that the public/private balance under article 15 should be struck with the primary objective of promoting and protecting human rights. This conclusion is based on the text of ICESCR itself. Article 15 should be read in conjunction with article 5 of ICESCR, which states that nothing in the Covenant can justify any act aimed at the destruction of any of its rights or freedoms or to limit a right beyond what is provided for in the Covenant.[5] In the context of article 15, this suggests that, whatever balance is struck between private and public interests in intellectual property, the balance should not work to the detriment of any of the other rights in the Covenant.[6] This position is also consistent with the Vienna Declaration and Programme of Action of the World Conference on Human Rights, which declares that "human rights are the first responsibility of Governments".[7]

14. Second, it is important to note the differing characteristics of intellectual property rights (IPRs) - copyright, patents, trademarks and so on - on the one hand, and human rights such as cultural rights on the other. Intellectual property rights are granted by the State according to well-defined criteria and so are more akin to a privilege. Those criteria are defined by national legislation. IPRs can be licensed or assigned to someone else, they can be revoked, and they eventually expire.[8] Similarly, IPRs can be - and often are - held by corporations. Human rights, on the other hand, are inalienable and universal. They are not granted by the State, they are recognized.

15. Nonetheless, intellectual property rights such as those contained in the TRIPS Agreement might be a means of operationalizing article 15, so long as the grant and exercise of those rights promotes and protects human rights. Determining whether the minimum standards contained in the TRIPS Agreement promote the enjoyment of human rights is a two-part exercise. First, the Agreement itself must be assessed for compatibility with a human rights approach. Second, the implementation of the Agreement must be assessed empirically to determine the effects of the Agreement on human rights in practice. The rest of this section focuses on assessing the TRIPS Agreement as a text from a human rights perspective.

### C. Links between human rights and the TRIPS Agreement

16. Upon scrutiny, there are potential links between human rights and the TRIPS Agreement. Article 7 of the TRIPS Agreement sets out its objectives. The article states that "(t)he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". The objectives therefore recognize a need for balance - balance between rights and obligations of technology holders, and between the interests of producers and users of technological knowledge, with the wider objective of promoting social and economic welfare.

17. The TRIPS Agreement attempts to achieve this balance in a number of ways. First, members may take measures to protect issues relevant to ICESCR, in particular health care, nutrition and the environment. For example, under article 8, members may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development". However, such measures are limited in the sense that they have to be consistent with the provisions of the TRIPS Agreement itself.[9] In relation to patent protection, members may exclude inventions from patentability in order to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.[10] Again, the article is limited by the proviso that such exclusions are possible so long as they are not made simply because the exploitation of the technology in question is prohibited by law.[11] Members may also exclude certain living matter from patentability, such as plants and animals, as well as methods for the treatment of humans or animals.[12]

18. Second, the TRIPS Agreement allows members to take measures to balance rights with responsibilities, indicating a degree of coherence with the balance required under article 15 of ICESCR. In relation to patents, members may authorize third parties to work the patent without

the authorization of the patent holder, subject to certain limitations.[13] This mechanism is generally referred to as a compulsory licence. The Agreement also envisages use by a government authority without the authorization of the patent holder, for example to protect the public interest. Similarly, members may take action against unfair or anti-competitive practices. According to the Principles of the Agreement, members may adopt appropriate measures to prevent the abuse of IPRs by right holders or to prevent the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.[14]

19. Third, the TRIPS Agreement encourages international cooperation. In particular, developed country members are obliged to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed countries[15] and to provide, on request, technical and financial cooperation in favour of developing and least developed countries.[16]

### D. A human rights approach to the TRIPS Agreement

20. Protecting public health and nutrition, protecting the environment, encouraging technology transfer, advancing socio-economic development as stated in article 7 of the TRIPS Agreement, and promoting fairness and international cooperation are measures that - at least in theory - are conducive to the promotion and protection of human rights and the balance sought under article 15. They call to mind the promotion of the right to food and to health, the right to development, and the right to enjoy the benefits of scientific progress. To use an analogy, any action taken against anti-competitive practices or the abuse of IPRs or of a dominant market position could be approximated to ensuring the human rights principles of equality, equal treatment and due process. The special and differentiated treatments offered to least developed countries perhaps equates with human rights notions of affirmative action as well as international cooperation under ICESCR, the Convention on the Rights of the Child[17] and the Declaration on the Right to Development.

21. Nonetheless, recognizing the links between the standards in the TRIPS Agreement and the promotion and protection of human rights is not the same as saying that the TRIPS Agreement takes a human rights approach to intellectual property protection. The primary question is whether the TRIPS Agreement strikes a balance that is consistent with a human rights approach. A few preliminary observations are made here.

22. It is clear that while links between the promotion and protection of human rights, on the one hand, and the rights covered by the TRIPS Agreement, on the other, exist, there remain fundamental differences of approach. First of all, the overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incentives. The various links with the subject matter of human rights - the promotion of public health, nutrition, environment and development - are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement. A human rights approach, on the other hand, would explicitly place the promotion and protection of human rights, in particular those in ICESCR, at the heart of the objectives of intellectual property protection, rather than only as permitted exceptions that are subordinated to the other provisions of the Agreement.[18] This is not to say that the protection of commercial objectives is necessarily incompatible with the promotion of human rights. Nonetheless, if we truly wish to

factor the promotion and protection of human rights into the objectives of the TRIPS Agreement, different ways and strategies of promoting and protecting scientific progress and its results should be explored in particular cases.

23. Second, while the Agreement identifies the need to balance rights with obligations, it gives no guidance on how to achieve this balance. On the one hand, the Agreement sets out in considerable detail the content of intellectual property *rights* - the requirements for the grant of rights, the duration of protection, the modes of enforcement. On the other hand, the Agreement only alludes to the *responsibilities* of IP holders that should balance those rights in accordance with its own objectives. The prevention of anti-competitive practices and the abuse of rights, the promotion of technology transfer, special and differential treatment for least developed countries are merely referred to - but unlike the rights it sets out, the Agreement does not establish the content of these responsibilities, or how they should be implemented. To illustrate the difference, a human rights approach might set out the minimum standards required for protection against anti-competitive practices or for the promotion of technology transfer to developing countries in much the same way as the Agreement now sets out minimum standards for the protection of patents or trademarks. Consequently, the balance identified in the TRIPS Agreement might not equate with the balance required under article 15 of ICESCR.

24. Third, like any international treaty, the TRIPS Agreement takes away a degree of autonomy from States, but it is appropriate to ask whether this affects States' abilities to promote and protect human rights, including the right to development. For example, one of the significant departures under the TRIPS Agreement from previous treaties on intellectual property rights is that the Agreement obliges WTO members to provide patent protection to cover all forms of technology, including pharmaceuticals.[19] This is a significant step. Prior to the TRIPS Agreement, States were free to decide what level of protection they would give to cover whatever forms of technology they saw as relevant to their development needs. Thus, measures to protect pharmaceuticals could be taken where national development, technological and health requirements suggested such action was beneficial. Such a position was in keeping with the Declaration on the Right to Development which declares that "States have the right and the duty to formulate appropriate national development policies that aim at the constant improvement of the well-being of the entire population and of all individuals, on the basis of their active, free and meaningful participation in development and in the fair distribution of the benefits resulting therefrom."[20] The TRIPS Agreement's obligation to provide protection for all forms of technology has an impact on States' ability to decide on development strategies.

25. Fourth, the protection contained in the TRIPS Agreement focuses on forms of protection that have developed in industrialized countries. For example, in the case of patents, the protection in the Agreement is most relevant to the protection of modern forms of technology, such as biotechnology, and most relevant to innovators situated in a selected number of industrialized countries.[21] This is reflected in the statistics, at least in the case of patents. World Bank figures relating to patent applications show an overwhelming presence of technology holders and applications in developed countries. For example, in 1997, patent applications in high-income countries numbered 2,785,420, while in East Asia and the Pacific they numbered 290,630; in the Middle East and North Africa there were only 1,716 applications and in sub-Saharan Africa only 392,959, with only 38 of those filed by residents.[22] In particular, IP protection is costly, not only to apply for, but also because of the need to pay maintenance

fees, to monitor the use of technology, and eventually to defend IPRs in the case of unauthorized use where necessary. The *Bulletin of the World Health Organization* has noted that many countries lack the technological infrastructure to benefit from costly IP systems directed to the promotion of modern technological research, thus making systems out of reach for many innovators or potential innovators in those countries.[23]

26. Further, no mention is made of the need to protect the cultural heritage and technology of local communities and indigenous peoples. While it might be the case that the negotiators of the TRIPS Agreement did not consider the protection of indigenous peoples' and local communities' knowledge, the emphasis on modern technology but not other forms of technology suggests an imbalance within the TRIPS Agreement that could have an impact on the enjoyment of human rights, in particular cultural rights. Focus on this issue has increased considerably since the adoption of the Convention on Biological Diversity in 1993.[24] Many of the forms of intellectual property protection contained in the TRIPS Agreement might be relevant to the protection of some of the knowledge of some local communities and indigenous peoples. However, there are still tensions between IP protection and the protection of the knowledge of local and indigenous communities. In particular, issues arise concerning the use of such knowledge by people outside the community without the knowledge holders' consent. Similarly, issues arise in relation to the equitable compensation for use of such knowledge where such use has led to the patenting of new knowledge. These tensions could require amendments, adaptations and additions to IP systems.

27. An overarching concern for a human rights approach to IP protection is what has become known as "TRIPS plus". WHO refers to "TRIPS plus" as a non-technical term which refers to efforts to "extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics".[25] The term "TRIPS plus" is also used to refer to situations where countries implement TRIPS-consistent legislation before they are obliged to do so. It does not refer to the situation where States introduce new forms of IP protection such as petty patents that are not included within the minimum standards of the TRIPS Agreements but that are geared towards providing incentives for research that are appropriate to local conditions. The use of trade pressure to impose "TRIPS plus"-style IP legislation has been noted before CESCR.[26] This could lead member States to implement IP standards that do not take into account the safeguards included under the TRIPS Agreement which could lead to IP systems that are inconsistent with States' responsibilities under human rights law.

28. However, even given these differences between a human rights approach and the TRIPS Agreement, much still depends on how the TRIPS Agreement is actually implemented. The TRIPS Agreement offers significant operational flexibility and the High Commissioner urges WTO member States to use this operational flexibility in ways that would be fully compatible with the promotion and protection of human rights. In this regard, it is important to note that out of 141 States members of WTO, 111 have ratified ICESCR.

## II. THE TRIPS AGREEMENT AND THE RIGHT TO HEALTH

### A. Introduction

29. The following section considers issues that can arise in the implementation of the Agreement, reviewing issues relevant to the operation of IP systems in the context of the right to health. The operational issues have been grouped under two main headings - medical research and access to drugs. While IP systems can affect the right to health positively in some cases, tensions may also arise. However, the TRIPS Agreement offers member States important operational flexibility. Implementing this flexibility within the TRIPS Agreement in accordance with the standards set for the promotion of the right to health under ICESCR will assist in avoiding these tensions. The following section examines first the obligations on States to respect, protect and fulfil the right to health. It sets out some of the concerns that have arisen in the context of existing IP systems and then discusses how the flexibility inherent in the TRIPS Agreement can be used to adjust IP systems so that they are consistent with the human rights obligations of WTO members.

### B. States' obligations to respect, protect and fulfil the right to health

30. Article 12 of ICESCR obliges States to respect, protect and fulfil the right of everyone to the highest attainable standard of physical and mental health.[27] CESCR has set out the content of that right in its General Comment No. 14 (E/C.12/2000/4), adopted on 11 May 2000. The General Comment sets out the content of the right, the obligations on States to respect, protect and fulfil the right, the elements of international cooperation relevant to implement the right, as well as acts constituting violations of the right. The following summary of the General Comment extracts those elements most relevant to a discussion of article 15 in the context of health. Of particular relevance are references to: the promotion of research; access to affordable treatments, in particular essential drugs; HIV/AIDS; national measures for the promotion of the right to health; clarification of international obligations; and acts that constitute violations of the right to health.

31. The right to health includes obligations on States to promote research. States are obliged to promote medical research, in particular with respect to certain categories of diseases including HIV/AIDS.[28] The obligation on States to fulfil the right to health includes the need for States to take positive measures including through fostering research into health-related areas.[29]

32. States are bound to promote the right to health through the ensuring access to affordable treatments. The right to health contains certain essential elements to be applied by States according to the prevailing national conditions. These elements include ensuring the availability, accessibility, acceptability and quality of health facilities, goods and services. The second element of accessibility includes the notion of affordability - health facilities, goods and services must be affordable for all, whether privately or publicly provided.[30] The General Comment also examines the specific steps that States should undertake in fulfilment of their obligations. Article 12 (2) (c) of ICESCR indicates that States parties to the Covenant must undertake steps necessary for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases". The control of diseases refers to States' individual and joint efforts to make available relevant technologies and the promotion of strategies of infectious disease control.[31]

The right to health includes a right to facilities, goods and services, under article 12 (2) (d). This obliges States to provide equal and timely access to basic preventive, curative and rehabilitative health services and appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at the community level. The right to facilities, goods and services also includes the provision of essential drugs.[32]

33. The right to health obliges States to take into account HIV/AIDS in respecting, protecting and fulfilling the right to health. The General Comment notes that formerly unknown diseases, such as HIV/AIDS and others, as well as the rapid growth of the world population have created new obstacles to the realization of the right to health which need to be taken into account when interpreting article 12.[33]

34. The General Comment sets out some of the national measures that States must take to implement the right. It notes that, as with other rights, States are obliged to respect, protect and fulfil the right to health. It states that "(t)he obligation to respect requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees. Finally the obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health".[34] Specifically, the General Comment states that "the obligation to *fulfil* requires States parties to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health".[35]

35. The General Comment sets out international obligations under the right to health. Specifically, States parties should recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health, taking into account the gross inequality in the health status of people, particularly between developed and developing countries.[36] States parties should ensure that the right to health is given due attention in international agreements and States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.[37] Similarly, States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health.[38] The General Comment recognizes that while States are ultimately responsible for compliance with the Covenant, all members of society, including the private business sector, have responsibilities regarding the realization of the right to health.[39] States parties to the Covenant also have international obligations to "provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs" and to "take measures to prevent, treat and control epidemic and endemic diseases".[40] Further, international organizations, including WHO and WTO, should cooperate effectively with States to build on their respective expertise in relation to the right to health.[41]

36. Finally, the General Comment notes certain acts that constitute violations of the right to health. Violations of the right to health can be the result of the actions of States, or the actions of other entities insufficiently regulated by the State.[42] Violations of the obligation to protect the right to health include the failure to regulate individuals, groups or corporations so as to prevent them from violating the right to health of others.[43] Violations of the obligation to fulfil the

right to health include, amongst others, the failure to adopt or implement a national health policy designed to ensure the right to health of all; insufficient expenditure which results in non-enjoyment of the right; and the failure to take measures to reduce the inequitable distribution of health facilities, goods and services.

### C. Operational aspects of IP systems - medical research

37. How compatible then is the protection and enforcement of IPRs with States' obligations to foster medical research? IPRs act as an incentive for the innovation of new technology, including pharmaceuticals. The forms of IP protection most relevant to pharmaceuticals are patents (on new medical products and processes), trademarks (covering signs distinguishing medical goods and services as coming from a particular pharmaceutical trader), and the protection of undisclosed information (in particular test data). Patents are particularly important for the pharmaceutical industry, first because the industry has to shoulder often very high costs for the testing, development and approval of drugs, and second, because pharmaceuticals are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of IP protection. It is likely that the possibility of obtaining patents on new drugs - and therefore a period of exclusivity to recover costs - acts as a major incentive to innovation in the pharmaceutical industry. While the incentive to innovate has the potential to promote the enjoyment of the right to health, this does not, ipso facto, justify the conclusion that IPRs promote respect for the right to health in all cases.

38. As IPRs are limited commercial rights, they are essentially driven towards economic reward; the objective of promoting respect for human rights would at best appear to be a secondary consideration. Two issues arise. First, as WHO has noted, the commercial motivation of IPRs means that research is directed, first and foremost, towards "profitable" disease. Diseases that predominantly affect people in poorer countries - in particular tuberculosis and malaria - still remain relatively under-researched.[44] The fact that patents create opportunities for economic reward that are optimized when market conditions are right logically leads researchers away from "unprofitable" diseases to diseases that affect people in markets where the return is likely to be greater. According to WHO, "questions remain as to whether the patent system will ensure investment for medicines needed by the poor. Of the 1,223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical disease".[45] This could mean that alternative mechanisms to patents might need to be considered by States in implementing articles 12 and 15 of ICESCR.

39. Second, again connected to the economic nature of IPRs, patents are increasingly becoming corporate assets, part of the stock of a company that reflects its competitiveness on the market. This can lead research into an innovation race. Consequently, while patenting activity is particularly high in the pharmaceutical industry, many patents cover "me-too" drugs - drugs that are just different enough to be considered novel for the purposes of patent protection, but in fact have similar effects as prior patented drugs. With "me-too" drugs, the economic gain for the patent holders is likely to be significant, but the question arises as to how the economic incentive of IPR simultaneously promotes the right to health in this situation. On the one hand, the presence of "me-too" drugs, even if patented, might lower the costs of drugs for consumers due to increased competition. On the other hand, it could result in the clogging of future research by the presence of too many patents, as well as a significant concentration of control over the

dissemination of drugs in the hands of certain corporations. This raises questions as to the effectiveness of patents as an operational mechanism for the implementation of article 15 (1) and 15 (3) of ICESCR.[46]

40. Similarly, the grant and exercise of IPRs can lead to undue restrictions on medical research which could run contrary to the requirement under article 15 of ICESCR to balance the protection of private interests with the promotion of the wide dissemination of medical knowledge. In particular, the practice of granting broad patents - an issue which has become particularly prevalent in the area of biomedical research - can lead to patents being used to block research efforts. The issue is relevant where research into a final product or process - for example, a drug - relies on several levels of innovation all of which are susceptible to IP protection. In such cases, patents on innovations from the early stages of research can be used to control and possibly block life-saving innovations that depend on the use of the first innovation.[47] Similarly, WHO has identified the situation where standards for the grant of patents can contribute to "ever-greening" - a process where minor innovations to patented innovations are themselves patented which can effectively extend the life of the patent beyond the original 20-year grant. Extending the active patent life beyond the limited period of protection could hold up other research efforts.[48] This could have implications for States' responsibilities to implement article 15 (3) of ICESCR.

41. Further, IPRs can affect the use of traditional medicines - in particular those of indigenous and local communities. Traditional medicines play an important role in the health care of all countries with up to 80 per cent of the world's population depending on traditional medications for its primary health care needs.[49] While the issues are highly complex, the High Commissioner notes two as particularly significant. First, while existing IP systems can promote the health innovations of these communities, the particular nature of this knowledge and the knowledge holders might require significant adaptation or amendments to be made to IP legislation for protection to be comprehensive. Second, traditional medicines have been appropriated, adapted and patented with little or no compensation to the original knowledge holders and without their prior consent.[50] This raises significant issues, not only in the field of the right to health, but also for the cultural rights of these communities and their members.[51] Further, it also raises the question of the effect of IP protection on the operation of the Convention on Biological Diversity, in particular its article 8 (j).

### D. Operational aspects of IP systems - access to drugs

42. The starting point for a consideration of the operational aspects of IP systems with regard to access to drugs is that access to essential drugs is a human right. While the protection and enforcement of IPRs can provide a more secure environment for the transfer of technology to developing countries, it can also provide a basis for charging higher prices for drugs and for technology transfer which can restrict access for the poor. In particular, the World Bank has noted that IPRs can sometimes prevent the distribution of potential international public goods helpful to poor countries, which can seldom afford the prices charged by patent owners.[52] In the context of HIV/AIDS, the Secretary-General recently stated that "we must put care and treatment

within everyone's reach. Even a year ago few people thought that effective treatment could be brought within reach of poor people in developing countries. ... People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off".[53]

43. There are many factors that influence access to drugs. WHO has recognized four principle factors: rational selection and use of drugs, affordable prices, sustainable financing, and reliable health and supply systems.[54] The presence of IP protection over drugs can play a role in determining the affordability of drugs. However, affordability of drugs also depends on other factors such as the level of import duties, taxes, and local market approval costs. In many cases, drugs will not be protected by IPRs, either because protection was not granted in the first place or because IPRs have expired. Even where drugs are protected by IPRs, the effect of IPRs on access to drugs can be varied. However, there is evidence to suggest that the effect of patents on affordability is significant with drug prices falling sharply when generic substitutes enter a market to compete with drugs upon patent expiry.[55]

44. In the context of HIV/AIDS treatments, high prices have had a substantial impact on impeding access for sufferers. UNAIDS has recognized that high prices affect access to treatments, in particular for the 95 per cent of sufferers who are in developing countries.[56] The problem becomes particularly acute as developing countries have a high dependence on private expenditure for the purchase of medicines compared to developed countries, in spite of their higher levels of poverty.[57] According to UNAIDS, the high prices of HIV treatments are due, in part, to patent protection which allows control over their manufacture and sale.[58] The UNDP Human Development Report 2000 notes that generic production of the HIV treatment flucanazole in India has kept the price at $55 for 150 milligrammes compared with $697 in Malaysia, $703 in Indonesia and $817 in the Philippines.[59] Similarly, a report to the CESCR has noted that the AZT treatment is produced at a supply cost of $48 a month in India as compared with $239 in the United States.[60]

45. The HIV/AIDS pandemic has a significant impact on the enjoyment of human rights. Not only does it concern the enjoyment of the right to health, it is also a significant obstacle to the realization of the right to development. Looking at the health dimension: in 1999, 5.4 million people were newly infected with HIV, 34.3 million people were living with HIV/AIDS throughout the world and 2.8 million people had died from the virus. A recent report of UNAIDS illustrates the developmental dimensions of HIV/AIDS. For example, surveys note that households caring for a family member with AIDS suffer dramatic decreases of income. In education, HIV is taking its toll, first by eroding the supply of teachers who fall ill as a result of the virus, second, by health treatment eating into family education budgets, third, by adding to the pool of children who are growing up without parental support which may affect their ability to stay at school. In the agricultural sector, sickness of farm workers has resulted in a fall in agricultural output and might threaten food security. HIV is hurting business through absenteeism, lower productivity, and higher overtime costs for workers obliged to work longer hours to replace sick colleagues.[61] Indeed, the effects of HIV on the enjoyment of the right to development are so strong that the Secretary-General in his address to the African Summit described HIV/AIDS as "our biggest development challenge".[62]

46. In light of the human rights dimensions of HIV/AIDS, accessing affordable HIV treatments has itself become a human rights issue. There are several ways in which access can be improved through lowering prices, including through the exchange of price information, price competition and price negotiation with public procurement and insurance schemes, price controls, reduced duties and taxes and improved distribution efficiency, reduced distribution and dispensing costs and reduced marketing expenses. Where HIV treatments are protected by IPRs, accessing affordable drugs will depend in part on how those rights are exercised. Specifically, strategies to be considered include differential pricing, parallel importation of drugs, and generic substitution of patented drugs.

47. Differential pricing has been defined as the adaptation, in some measure, of prices to the purchasing power of consumers in different countries.[63] This could mean, for example, pricing HIV drugs at lower rates for developing countries but maintaining prices in developed country markets. The logic behind differential pricing is that higher prices can be shared in wealthy markets that can afford them, while letting poorer countries enjoy lower prices. However, one of the perceived problems with differential pricing is the possibility of low-price drugs being diverted towards wealthy markets. In the case of patented pharmaceuticals, this would lessen the opportunity to exercise IPRs as a means of recouping costs. Consequently, effective strategies to maintain higher prices in wealthy markets so that developing countries can benefit from cheaper drugs will have to be considered as part of any differential pricing strategy - possibly through some form of market segmentation. There are many ways in which market segmentation might be achieved. Where treatments are protected by IPRs, drug licensing agreements with geographical restrictions could be used so that cheaper drugs do not leak back to wealthier markets.[64] Nonetheless, many questions still remain concerning differential pricing, on the practical level. In particular, it is unclear to what extent people in wealthy countries, as well as insurance companies in wealthy countries, would accept continuing to pay high prices for drugs when lower prices are systematically being offered elsewhere. There are also questions at the practical level concerning the coexistence of differential pricing and parallel importation.

48. Another means of improving access to cheaper drugs is through parallel importation. Parallel importation has been described as importation, without necessarily having the consent of the patent holder, of a product legally marketed in another country by the patent holder or by another authorized party.[65] Thus, where a patented drug is marketed at a cheaper price in one country, another country can benefit from the cheaper drugs through importing them rather than pay the more expensive equivalent directly from the patent holder. This is possible because the patent holder's rights to control the import and export of drugs are "exhausted" once they have been placed on the market.

49. Similarly, access to affordable drugs can be improved by encouraging the production of generic substitutes. Where drugs are patent protected, generic supply must wait until expiry of the patent term. However, States may encourage generic production by taking appropriate legislative action, including through the inclusion of exceptions to patent rights which permit early testing and approval of generics prior to the expiry of the IRPs.[66] However, it is possible to produce generic substitutes even where the patent is still current. This can be achieved by a government authority issuing a compulsory licence for the patented drugs. A compulsory licence is a non-exclusive licence to produce patent rights that is granted to a third party by authorization of a government authority, irrespective of the will of the patent owner.[67] The

patent owner will receive a reasonable remuneration in return, at a rate set by the authority. Compulsory licences are generally awarded to promote the public interest or in cases of national emergency. While compulsory licences are not geared towards establishing technology partnerships between patent holders and users, they can be useful in providing a local producer the means of supplying needed drugs at cut rates. Further, the provision for the award of compulsory licences in local legislation can be an effective negotiating tool. Hesitant patent holders might be encouraged to enter voluntary licence agreements or produce needed drugs locally in order to avoid the possibility of an award of a compulsory licence.[68]

50. At the same time, IPRs such as trademarks can be a useful tool to assist consumers and medical practitioners to identify the source and quality of pharmaceuticals. Trademarks can be particularly useful to help consumers and medical practitioners ensure the source of drugs where generic drugs are allowed to be marketed without appropriate approval and testing procedures. Drugs that do not meet appropriate standards can prolong treatment periods, exacerbate conditions being treated, cause death and help create drug resistance.[69] This means that it is particularly important to ensure that trademarks are not counterfeited - that is, used on pharmaceuticals not produced by the particular trader that owns the trademark.[70]

## E. The provision of HIV treatments in Brazil

51. In response to the note verbale sent on 6 March, the Government of Brazil supplied information on its HIV programme, the role played by its IP law and the impact of its health policy. The other responses - not relating specifically to the right to health - have been compiled in the report of the Secretary-General (E/CN.4/Sub.2/2001/12). According to the Brazilian Ministry of Health, there are currently 536,000 people with HIV in Brazil; there have been 196,000 notified cases of AIDS and 95,000 deaths; 85,000 people are currently receiving approved combination therapies for HIV under the Brazilian Free Distribution of AIDS Drugs for All programme.

52. Currently, the Ministry of Health is providing 12 different pharmaceuticals as the basis of the combination therapy, 7 of which are produced in Brazil - the other 5 are imported. The advantages of local production are significant. Today, the Government spends US$ 319 million on purchasing local and imported drugs to supply its HIV programme. The Ministry of Health estimates that if all those drugs had been imported, the cost to the Government would be in the range of US$ 530 million which, according to the Ministry, would make the programme unviable. It should be noted that Brazil already spends 56 per cent of the US$ 305 million spent annually on its HIV programme on the 5 imported drugs included in the 12 drugs comprising the "cocktail".

53. Of the 12 therapies, 2 are protected by patents in Brazil (Efivirenz and Nelfinavir, held by Merck Sharp & Kohme and Roche, respectively). While some of the seven drugs produced locally are protected by off-shore patents, production began before 1997 (the year in which the Brazilian patents law entered into force) so the local production does not infringe the rights of overseas patent holders. However, significant expenditures are incurred in relation to the purchase of the two patented drugs. The Ministry of Health indicates that purchase of the two patented drugs through importation has alone consumed 36 per cent of the resources of the HIV treatment budget. With the appearance of new and more effective drugs for combating AIDS,

the Ministry of Health estimates that more expensive drugs protected by patent will slowly begin to comprise the combination therapy. This development, according to the Ministry of Health, could place their HIV treatment programme at risk.

54. For this reason, the Brazilian Government has sought ways to encourage the international pharmaceutical industry to enter negotiations for the sale of drugs, taking into account the purchasing power of particular markets - in this regard, Brazil makes specific reference to the UNDP Human Development Index as an indication of relevant purchasing strength. To do this, the Government notes that it will employ all available resources in Brazilian legislation - while observing the international undertakings entered into by Brazil - to make drugs accessible to their citizens. Part of this strategy has involved the Brazilian Intellectual Property Law which came into force in 1997.

55. The Brazilian IP law allows a government authority to issue a compulsory licence where a patent holder exercises patent rights in an abusive manner, or by means of an abuse of economic power proven by an administrative or court decision. There are certain other instances where compulsory licences may be issued, including under article 71, in cases of national emergency or public interest.[71] The terms "national emergency" and "public interest" are defined in the Presidential Decree on Compulsory Licensing (1999).[72] According to the decree, "(a) national emergency is understood to be a condition of impending danger to the public, even if existing only in a part of the national territory". Further, "(t)here are considered to be within the public interest those facts, among others, related to the public health, nutrition, protection of the environment, as well as those of primordial importance to the technological or social and economic development of this country". This links closely with provisions of the TRIPS Agreement which allow for use of a patent without the authorization of the right holder in certain circumstances, including "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".[73]

56. The existence of these safeguard provisions has been helpful in improving the implementation of the Brazilian HIV treatment programme. While no compulsory licence has been issued under the Brazilian IP law, the provisions have been useful in negotiations with patent holders. The use of rights over the two patent drugs Efivirenz and Nelfinavir are cases in point. In the case of Efivirenz, the Government had begun research into the drug with the aim of achieving full capability to manufacture it locally.[74] With local manufacture in mind, a request to issue a compulsory licence for the drug had also been submitted. Since the agreement with the patent holder, the request for a compulsory licence has been put on hold, but research is continuing in case the Government finds it necessary to issue a compulsory licence in the future. In the case of Nelfinavir, negotiations for a decrease in prices are continuing. As negotiations continue, the Government is continuing research into the production of the drug and the Ministry of Health has indicated that, if negotiations do not lead to a significant decrease in price, it will consider requesting a compulsory licence so that Nelfinavir can be produced by national laboratories.

57. The results of the Brazilian strategy have been significant. In terms of the enjoyment of Brazilians' right to health, there has been a reduction in deaths due to AIDS by 50 per cent over the last four years. Further, there has been a reduction of 80 per cent in cases of hospitalization due to opportunistic diseases with a reduction in the appearance of the most serious opportunistic

diseases tuberculosis (by 60 per cent), citomegalovirus (by 54 per cent) and Kaposis sarcoma (by 38 per cent). The programme has also made economic sense. The reduction in hospitalizations has saved the Ministry of Health US$ 422 million. Moreover, costs of funding the programme are coming down. In 1999, the Ministry of Health spent US$ 336 million on drugs to reach 73,000 patients. In 2000, the Ministry spent the lower amount of US$ 319 to meet the needs of 85,000 patients. Local production of generic drugs has led to production cost cuts of, on average, 70 per cent (the reduction in the price of Zalcitabina (ddC) has been 95 per cent) and the Government has even achieved a reduction in the price of imported drugs of an average of 10 per cent. In the longer term, the programme has improved local technological and research capacity, which could enable it in the future to assist developing countries struggling with the HIV/AIDS pandemic, in particular countries in Africa.

58. On the facts that have been provided by the Government of Brazil, it is possible to say that the Brazilian case demonstrates how the provisions of the TRIPS Agreement can be implemented in ways that respect, protect and fulfil the right to health. Through careful legislative implementation of TRIPS provisions - in particular article 31 on compulsory licensing - article 71 of the Brazilian IP law supports the implementation of national health policy aimed at providing essential drugs to those who need them. Furthermore, by implementing the public health safeguards in the TRIPS Agreement, the Brazilian Government has successfully married implementation of the Agreement with its obligations under human rights law - in particular its duty to provide affordable essential drugs.

## III. CONCLUSIONS AND RECOMMENDATIONS

59. What then are the obligations on States? On the one hand, the TRIPS Agreement encourages States to implement IP systems that promote economic and social development taking into account the need to balance rights with responsibilities. The Agreement allows members to take measures to protect the public interest, including the promotion of public health. Article 15 of ICESCR requires States to balance public and private interests in the design of IP protection. General Comment No. 14 on article 12 of the ICESCR indicates the measures that States should take with regard to the promotion of the right to health, including: the promotion of research; ensuring access to affordable essential drugs; the adoption of specific measures in relation to HIV/AIDS; and the promotion of international cooperation to implement the right to health.

60. Out of the 141 members of WTO that have undertaken to implement the minimum standards of IP protection in the TRIPS Agreement, 111 have ratified ICESCR. Members should therefore implement the minimum standards of the TRIPS Agreement bearing in mind both their human rights obligations as well as the flexibility inherent in the TRIPS Agreement, and recognizing that "human rights are the first responsibility of Governments". In light of this, the High Commissioner believes that implementation of the TRIPS Agreement should be characterized by the following objectives.

61. The promotion of article 15 of ICESCR. States, in implementing systems for IP protection, are encouraged to consider the most appropriate mechanisms that will promote, on the one hand, the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications and, on the other hand, the right of everyone to benefit

from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. In this sense, **the High Commissioner encourages States to monitor the implementation of the TRIPS Agreement to ensure that its minimum standards are achieving this balance between the interests of the general public and those of the authors. The High Commissioner supports the WHO statement that "countries are advised to carefully monitor the implementation of the TRIPS Agreement in order to formulate comprehensive proposals for the future review of the TRIPS Agreement ...".**[75]

62. The promotion of the right of all to enjoy the benefits of scientific progress and its applications.[76] The design of IP systems should take into account the fact that the grant of overly broad patents can be used to block future medical research. The design of IP systems should, in calculating the difficult trade-off between public and private interests, take into consideration that the increasing tendency to grant patents for "me-too" drugs may run counter to the primary objective of IP systems to promote innovation, and focus too heavily on promoting private commercial interests. The requirements under the TRIPS Agreement for the grant of patents - novelty, inventive step and industrial applicability[77] - are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, **the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge under article 15.**

63. The promotion of the right to health. **The High Commissioner supports WHO's call that "(w)hen establishing standards of patentability for pharmaceuticals, countries should consider the implications for health of those standards".**[78]

64. The prevention of the abuse of IPRs.[79] Patents can be used to block medical research and development efforts, which calls into question their impact on economic and social welfare. Articles 8 and 40 of the TRIPS Agreement allow member States to protect against anti-competitive practices. **The High Commissioner encourages States to consider the elaboration of competition laws that prevent abuses of IPRs that lead to violations of the right to health - in particular restrictive licensing practices or the setting of high prices for essential drugs.**

65. The protection of the cultural rights of indigenous peoples and local communities.[80] The TRIPS Agreement does not refer specifically to the protection of the innovations of local and indigenous communities - a fact which indicates the Agreement is tipped in favour of the protection of modern technology but not of other forms. The report on the WHO Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine recommends that "(e)fforts should be made to utilize the flexibility in the TRIPS Agreement to promote easy access to traditional medicine for the health care needs of developing countries".[81] The report also recommends that the ways and means need to be devised and customary laws strengthened for the protection of traditional medicine knowledge from biopiracy.[82] **The High Commissioner encourages the adaptation of IP systems so that they fully take into account cultural and other rights of indigenous and local communities.**

66. The promotion of access to affordable essential drugs. Several provisions in the TRIPS Agreement offer flexibility that could be useful in promoting access to affordable essential drugs. Importantly, article 31 allows States to grant compulsory licenses for patents so long as certain conditions are fulfilled. Article 31 holds significant potential for the protection of the public interest in areas such as the promotion of the right to health. Similarly, the TRIPS Agreement does not prohibit members from allowing parallel importation of patented pharmaceuticals. Article 6 of the Agreement specifically states that the "exhaustion" of IPRs shall not be subject to dispute settlement under the Agreement. **The High Commissioner encourages member States to implement these provisions in national legislation as safeguards to protect access to essential drugs as a component of the right to health as well as other human rights.**

67. The promotion of international cooperation in the implementation of the TRIPS Agreement.[83] International cooperation is an important ingredient in the promotion and protection of human rights. The Secretary-General has emphasized the particular need for international cooperation in the context of HIV/AIDS and has proposed the establishment of a global fund dedicated to the battle against HIV/AIDS and other infectious diseases. In this context he has encouraged developing countries to exploit all options including the production and importation of "generic" drugs.[84] Article 66 (2) of the TRIPS Agreement, obliges developed country members to provide incentives to enterprises and institutions in their territories to promote technology transfer to least developed countries - a provision which could be used beneficially to promote access to affordable drugs for least developed countries. **The High Commissioner encourages developed countries to establish clear incentives to promote technology transfer and the supply of affordable drugs to developing countries.**

68. The promotion and protection of all human rights. An important aspect of the human rights approach to IP protection is the express linkage of human rights in relevant legislation. Express reference to the promotion and protection of human rights in the TRIPS Agreement would clearly link States' obligations under international trade law and human rights law and would parallel the Secretary-General's call in 1997 to mainstream human rights throughout the United Nations system. This would assist States to implement the "permitted exceptions" in the TRIPS Agreement in line with their obligations under ICESCR. To this end, the High Commissioner intends to seek observer status at the TRIPS Council. **The High Commissioner also encourages the Fourth Ministerial Meeting of the World Trade Organization in Qatar in November 2001 to consider establishing closer links between the promotion and protection of human rights and the TRIPS Agreement. In the event of a renegotiation of the Agreement, this could be achieved through an express reference to human rights in article 7.**

69. IP legislation that maintains flexibility and a balance of rights with responsibilities. **The High Commissioner joins WHO in recommending that developing countries be cautious about enacting "TRIPS plus" legislation that is more stringent than present requirements under the TRIPS Agreement without first understanding the impact of such legislation on the protection of human rights.**[85]

70. The High Commissioner also makes specific recommendations to the Sub-Commission on the Promotion and Protection of Human Rights. Section I of the present report identifies a human rights framework for analysing the TRIPS Agreement. While this report has focused on the right to health, the same analysis could be applied to the right to food, the right to development, and the rights of indigenous peoples. The analysis could also be applied to the grant and use of IPRs in relation to the human genome project. **The High Commissioner therefore recommends**:

**(a) That the Sub-Commission consider requesting further reports on the impact of the TRIPS Agreement on other specific human rights;**

**(b) That the Sub-Commission consider recommending that the Commission on Human Rights convoke an expert seminar to consider the human rights dimensions of the TRIPS Agreement, based on the present report and any others that might be commissioned in the future.**

Notes

[1] The resolution notes that "actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights in relation to, inter alia, impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food ... and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health".

[2] The TRIPS Agreement, article 66 (1).

[3] ICESCR, article 15 (1), states: "The States Parties to the present Covenant recognize the right of everyone: (a) to take part in cultural life; (b) to enjoy the benefits of scientific progress and its applications; (c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author."

[4] One way of determining the balance under human rights law is by looking at the *travaux préparatoires* - the debates that led to the eventual inclusion of the right in the Universal Declaration and ICESCR. A report (E/C.12/2000/15) submitted to the Committee on Economic, Social and Cultural Rights (CESCR), the monitoring body of the Covenant, reviewed the *travaux préparatoires* of both the Universal Declaration and ICESCR. The review concluded that, in fact, little attention was given to this issue at the time. At best, it is possible to surmise that the drafters placed a greater emphasis on promoting public interests in accessing new creations and inventions than on protecting private interests over intellectual property. The debates demonstrated a range of positions. The protection of the moral and material interests of authors was given some attention - with the focus on copyright protection, and to a lesser extent patents. However, attention was overwhelmingly placed on the right to have wide public access to innovations and creations; copyright and patents were not seen in terms of international limits on the rights of everyone to benefit from new knowledge and technology. The report further suggested that the debates concerning authors focused almost entirely on authors as individuals

and did not consider article 15 in terms of corporately held patents, or, indeed, of authors as employees of corporate rights-holders. The report also observed that it is unlikely that the drafters would have imagined the key role that intellectual property rights (IPRs) would later play in the fields of trade, development, health or food. See Maria Green "Drafting history of article 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights", 9 October 2000, in particular paragraph 45.

[5] ICESCR, article 15 (1) states that "(n)othing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights or freedoms recognized herein, or at their limitation to a greater extent than is provided for in the present Covenant".

[6] This objective of article 15 has also been recognized before the CESCR. See E/C.12/2000/12, para. 31.

[7] A/CONF.157/23, article 1.

[8] Some States recognize moral rights of authors to their works that are in fact inalienable. According to article 6 bis of the Berne Convention for the Protection of Literary and Artistic Works (1896), moral rights are referred to as follows: "Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honour or reputation".

[9] The TRIPS Agreement, article 8, "Principles".

[10] Ibid., article 27 (2).

[11] Ibid.

[12] The TRIPS Agreement, article 27 (3) (b), states that members may also exclude from patentability: "(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes ..."

[13] The TRIPS Agreement, article 31.

[14] Ibid., article 8 (2), "Principles". See also article 40 in section 8, "Control of anti-competitive practices in contractual licences".

[15] Ibid., article 66 (2), "Least developed countries".

[16] Ibid., article 67, "Technical cooperation".

[17] Article 4. The Convention on the Rights of the Child has been ratified by 191 States - all but two - and is therefore the most widely ratified binding human rights treaty.

[18] A. Chapman, "Approaching intellectual property as a human right: obligations related to article 15 (1) (c)" (E/C.12/2000/12), para. 33. As Chapman has noted: "Intellectual property law should incorporate explicit human rights and ethical provisions as criteria for the evaluation of applications for patents and trademarks and develop an institutional mechanism capable of making these determinations. In most cases, patent and trademark offices are not competent to undertake such a review and are inclined to subordinate human rights considerations to an economic calculus".

[19] The TRIPS Agreement, article 27 (1) states: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

[20] Declaration on the Right to Development, article 2 (3). See also article 1 (2) of ICESCR which states that "All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic cooperation ..." See also article 1 (2) of the Declaration which states that the "human right to development also implies the full realization of the right to self-determination which includes ... the exercise of their inalienable right to full sovereignty over all their natural wealth and resources".

[21] For example, members are obliged to provide protection for new plant varieties either by patents or by an effective *sui generis* system or a combination of the two. The TRIPS Agreement, article 27 (3) (b).

[22] World Bank, World Development Indicators 2000, World Bank, Washington DC, table 5.12.

[23] Carlos M. Correa, "Health and Intellectual Property Rights", Bulletin of the World Health Organization, 2001, 79 (5), p. 381.

[24] See in particular article 8 (j) of the Convention which states that parties to the Convention are required to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity".

[25] "Globalization, TRIPS and access to pharmaceuticals", WHO Policy Perspectives on Medicines: WHO Medicines Strategy: 2000-2003, No. 3, March 2001 (WHO/EDM/2001.2), p. 4.

[26] Chapman, op. cit., para. 71. Chapman's paper to the Committee notes that pressure to implement TRIPS plus provisions has been applied to Brazil, Ecuador, India, Pakistan, South Africa and Thailand.

[27] Article 12 (1) states that "(t)he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standards of physical and mental health". Article 12 (2) states that "(t)he steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) the improvement of all aspects of environmental and industrial hygiene; (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness".

[28] General Comment No. 14 (2000), para. 36.

[29] Ibid., para. 37.

[30] Ibid., para. 12 (b).

[31] Ibid., para. 16.

[32] Ibid., para. 17.

[33] Ibid., para. 10.

[34] Ibid., para. 33.

[35] Ibid., para. 36.

[36] Ibid., para. 38.

[37] Ibid., para. 39.

[38] Ibid.

[39] Ibid., para 42.

[40] Ibid., paras. 43 and 44.

[41] Ibid., para. 64.

[42] Ibid., para. 48.

[43] Ibid., para. 51.

[44] P. Drahos, Human Rights, "Globalisation and intellectual property rights", paper presented at the Workshop on international trade, finance and investment and economic, social and cultural rights: the role of the Committee on Economic, Social and Cultural Rights in a Globalizing Economy, Geneva, 6 May 2000, p. 7.

[45] WHO/EDM/2001.2, op. cit., p. 5.

[46] Article 15 (3) states that "the States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity".

[47] M.A. Heller and R.S. Eisenberg, "Can Patents Defer Innovation? The Anticommons in Biomedical Research", Science, 1 May 1998, vol. 280, pp. 698-701, www.sciencemag.org

[48] WHO/EDM/2001.2, op. cit., p. 2.

[49] WHO, Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, Bangkok, 6-8 December 2000 (WHO/EDM/TRM/2001.1), p. 2.

[50] Ibid., p. 34.

[51] See, e.g., Chapman, op. cit. For example, Chapman notes the case of a small United States company that took out a US plant patent on a variety of ayahuasca (a plant with medicinal qualities) native to the Amazonian rainforest. In 1999, a coalition of environmental groups objected to the patent because it appropriated a plant that is considered sacred to many indigenous peoples from the region. The patent was voided due to lack of novelty and distinctiveness; however, the US Patent Office did not acknowledge the argument that the plant's religious value warranted an exception from patenting.

[52] World Bank, World Development Report 2000/2001, World Bank, Washington DC, p. 184.

[53] "Secretary-General proposes global fund for the fight against HIV/AIDS and other infectious diseases at African leaders summit", SG/SM/7779/Rev.1-AFR/313/Rev.1-AIDS/7/Rev.1, 26 April 2001, http://www.un.org/News/Press/docs/2001/SGSM7779R1.doc.htm

[54] WHO, "More equitable pricing for essential drugs: What do we mean and what are the issues?", background paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Hösbjör, Norway, 8-11 April 2001, p. 9.

[55] Watal, Jayashree, "Workshop on differential pricing and financing of essential drugs", background note prepared by Jayashree Watal, consultant to the WTO secretariat, p. 14.

[56] High prices are not the only reason behind the limited access to HIV treatments. Other reasons include limitations in infrastructure for diagnosis and treatment, lack of epidemiological data on the patterns of opportunistic diseases, gaps in the supply system and poor financing. See UNICEF/UNAIDS/WHO/EDM/MSF project, "Selected drugs used in the care of people living with HIV: sources and prices", October 2000, p. 1.

[57] Watal, op. cit., p. 9, notes that private expenditures in developing countries constitute 70-90 per cent of pharmaceutical expenditures, but only 40 per cent in developed countries.

[58] UNAIDS, Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference, Seattle, 30 November-3 December 1999 http://www.unaids.org

[59] UNDP, Human Development Report 2000, Oxford University Press, New York, 2000, p. 84.

[60] Chapman, op. cit., para. 63. It should be noted that prices for pharmaceuticals are influenced by many factors, not only the use of IPRs. Factors could be influenced by Government regulation, the exchange rate, the costs of drug testing and approval, retail overheads, the existence of tariffs and so on.

[61] UNAIDS, Report on the Global HIV/AIDS Epidemic, Geneva, June 2000, (UNAIDS/00.13E), p. 26 ff.

[62] Op. cit. at note 53.

[63] Watal, op. cit., p. 11.

[64] Ibid., p. 18.

[65] WHO/EDM/2001.2, op. cit. p. 4.

[66] Ibid., Correa, op.cit., p.381, notes that Argentina, Australia, Canada, Israel and the United States of America all have legislation allowing this exception.

[67] It should be noted that under article 31 of the TRIPS Agreement, it is still necessary to enter negotiations for authorization with the patent holder - except in the case of a national emergency or extreme urgency.

[68] For a more detailed discussion on compulsory licensing provisions in the TRIPS Agreement, see World Trade Organization, "Environment and TRIPS", Committee on Trade and Environment, 8 June 1995 (WT/CTE/W/8).

[69] WHO, Revised drug strategy: report of the secretariat A/54/17, 10 April 2001, para. 25.

[70] The TRIPS Agreement includes provisions to fight against counterfeiting, and includes provisions for international cooperation to fight counterfeiting. See in particular Part III of the TRIPS Agreement, "Enforcement of Intellectual Property Rights", and article 69 entitled "International cooperation".

[71] Intellectual Property Law (1996) Brazil, No. 9,279, article 71 of which states: "In cases of national emergency or public interest, declared in an act of the Federal Authorities, insofar as the patentee or his licensee does not meet such demand, a temporary non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee."

[72] Presidential Decree on Compulsory Licensing (1999) Brazil, No. 3,201, article 2.

[73] See in particular the TRIPS Agreement, article 31 (b). See also article 8.

[74] The TRIPS Agreement, article 30, states that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." The provision is generally accepted as including the use of patents for research purposes.

[75] WHO/EDM/2001.2, op. cit., p. 6.

[76] ICESCR, article 15 (1) (b).

[77] The TRIPS Agreement, article 27 (1).

[78] WHO/EDM/2001.2, op. cit., p. 1.

[79] ICESCR, article 15 generally - i.e. the balance of private and public interests aimed at promoting the enjoyment of human rights

[80] ICESCR, article 15.

[81] WHO/EDM/TRM/2001.1, op. cit., p. 35.

[82] Ibid, p. 34. For example, this could include taking action through national legislation to prevent the acquisition of IPRs over traditional medicine by its documenting and publication or inclusion in a database. This could help prevent the patenting of traditional medicines by third parties by demonstrating that the drug or treatment is not "new".

[83] ICESCR, article 12 and article 2 (1). Article 2 (1) states that "Each State Party ... undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, ... with a view to achieving progressively the full realization of the rights recognized in the present Covenant ..."

[84] Op. cit., at note 53.

[85] WHO/EDM/2001.2, op. cit., p. 4.

---